



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,392	02/23/2004	Ryan P. Boucher	1759.15103-CIP 2 DIV	8431
26308	7590	01/18/2007	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			YANG, ANDREW	
		ART UNIT	PAPER NUMBER	
		3733		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	01/18/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,392	BOUCHER ET AL.	
	Examiner	Art Unit	
	Andrew Yang	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 December 2006.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 23 February 2004 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/23/2004.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application
6) Other: _____.

DETAILED ACTION

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/088459 and 09/420529, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Boucher et al. claim a method of wrapping an expandable structure prior to insertion into bone. Applications 09/088459 and 09/420529 do not teach a structure in the disclosure capable of anticipating the claimed method.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 402. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if

only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

On page 3, line 4, "is" should be changed to -- its --.

On page 11, line 9, "54" should be changed to -- 24 --.

On page 28, line 26, "76" should be changed to -- 78 --.

On page 33, lines 17, 20, 26, and on page 34, line 16, "56" should be changed to -- 56A --.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Osorio et al. (U.S. Patent 6726691).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Osorio et al. discloses a device for treating fractured or diseased bone comprising a balloon catheter 200 having opposite ends (Figure 5c) and an expandable structure 210. The balloon catheter 200 is folded to fit through the hollow interior of a shaft 348 and into a vertebral body. Also, the balloon catheter 200 can be wrapped around tube 205 by rotating cap 310, thereby causing the expandable structure to twist relative to the fitting 220 prior to insertion and withdrawal (Column 14, Lines 48-49). Once in the desired position the expandable structure 210 is filled with a pressurized filling medium (Column 8, Lines 45-50) and causes the expandable structure 210 to press against the cancellous bone, thereby forming a compressed bone region and if sufficient pressure is available pressures capable of moving fractured cortical bone can be developed (Column 9, Lines 17-33). After the cavity is formed in the cancellous bone, a material is introduced through shaft 348 into the vertebral body under low pressure (Column 9, Lines 33-34). The material can consist of bone cement, synthetic bone substitutes, hydroxyapatite epoxy, or other appropriate filling materials.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (U.S. Patent No. 4969888) in view of Schiff (U.S. Patent No. 4467790).

Scholten et al. discloses a device for fixation of osteoporotic bone comprising a structure consisting of a balloon 76 and neck 77 with opposite ends spaced along an axis (Figure 22 and 23). The balloon 76 is inserted into the vertebral body via cannula 30 created by soft tissue expander 70 and inflated. As a result the balloon 76 compacts the bone marrow leaving a void or cavity to be treated (Column 7, Lines 17-21). The balloon 76 is then deflated and removed, at which time synthetic bone or methyl methacrylate cement is injected into the cavity. Scholten et al. fails to disclose wrapping the structure prior to insertion, unwrapping it after being inserted, then wrapping it once again before the structure is removed from the bone, wherein wrapping the structure includes causing differential rotation of one end of the structure about the axis relative to the other end. Schiff teaches a balloon 12 joined to a catheter at a proximal end, which is wrapped around a stylet 30 and then inserted percutaneously through sheath 40. Once in the operative position the balloon is untwisted and thus completing the insertion operation (Column 6, Lines 52-55). The balloon can then be removed upon completion

of the procedure by deflating the balloon 12 and re-wrapping it and pulling it back through sheath 40. The balloon is twisted by rotating knob 28 in a clockwise direction with the balloon 12 held in place at location 50, while the tip 14 is gently rotated to assist with the wind (Column 5, Lines 60-64). The twisting significantly reduces the outer diameter of the balloon, making it extremely advantageous for percutaneous insertion through a small diameter sheath (Column 2, Lines 27-31). It would have been obvious to one skilled in the art at the time the invention was made to construct the balloon of Scholten et al. capable of being wrapped prior to insertion and removal in view of Schiff so that it would have the advantage of being able to fit through a sheath with a small diameter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4261339, 5102390.

Any inquiry concerning this communication from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached Monday-Friday 7:30 am – 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Eduardo Robert can be reached at 571-272-4719. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private Pair only. For More information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact Electronic Business Center (EBC) at 866-217-9197 (toll free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (USA OR CANADA) or 571-272-1000.

A.Y.

12/27/2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER